UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

v.

LAURENCE F. DOUD III,

Defendant.

Case No. 19 Cr. 285 (GBD)

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT LAURENCE F. DOUD'S MOTION TO DISMISS COUNT ONE OF THE INDICTMENT (NARCOTICS CONSPIRACY)

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Pursuant to Federal Rule of Criminal Procedure 12(b)(3)(B) and the Fifth Amendment of the Constitution, Defendant Laurence F. Doud III, by and through his undersigned counsel, Gottlieb & Janey LLP, hereby moves to dismiss Count One (Narcotics Conspiracy) of the Indictment ("Count One"), which charges violations of 21 U.S.C. § 841 and 21 U.S.C § 846. Count One is defective because 21 U.S.C. § 841 does not apply to Mr. Doud as an employee of a wholesale drug distributor. Further, the charge is unconstitutionally vague as applied to Mr. Doud. Given the prosecutions under the statute over the past 40 years, as well as the recent amendments to the statute, it is impossible that Mr. Doud would have had the requisite notice that he could be prosecuted under 21 U.S.C. § 841.

I. PRELIMINARY STATEMENT

Count One of the Indictment must be dismissed as there is no legal basis upon which to charge Mr. Doud with conspiracy to illegally distribute substances under 21 U.S.C. §§ 841 and 846. We cannot identify any instance in which an employee of a Drug Enforcement Agency ("DEA") registered distributor has been prosecuted under these statutes. To be clear, registrants and employees of registrants have been prosecuted under 21 U.S.C. §§ 841 and 846; however, unlike the instant case, those prosecutions involve individuals who were *directly* involved in either a **medical practice or a pharmacy**, not an individual substantially in a different point of the drug distribution value chain such as at the wholesale distributor.

Over the past 40 years, 21 U.S.C. § 841 has been expanded by the courts to apply to the medical and pharmacy professions and those directly linked to them to enforce the prescribing of controlled substances only "for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." *See U.S. v Moore*, 423 U.S. 122, 136 (1975)

(recognizing that a defendant doctor could be prosecuted under 21 U.S.C. § 841 when violating his or her duties with respect to issuing prescriptions). Such prosecutions have included doctors, nurses, pharmacists, and owners of pharmacies, specifically because they are on the front line of the prescription process. Specifically, they have medical knowledge, interact with patients, or at the very least, work directly with the medical professionals who do. These amendments have been made in recognition of the fact that medical professionals are most directly responsible for enabling the diversion of drugs from legitimate channels to illegitimate channels. Even very recent amendments—in 2018—to the Controlled Substances Act ("CSA") that were specifically passed in light of the growing opioid crisis did not expand the scope of 21 U.S.C. § 841 to explicitly include employees at the distribution level. Congress could have taken that step but did not. Instead, with respect to wholesale distributors, the recent amendments focused on strengthening the requirements to detect and report suspicious orders.[1]

Prior to these amendments, the statutory text of the CSA did not specifically require registrants to design and operate a system to disclose any suspicious orders of controlled substances and to report such orders to the DEA; rather, such requirements appeared in the Federal Regulations.[2] These amendments added a new section to the CSA entitled "Suspicious Orders," requiring a DEA registrant to design and operate such a system.[3] Nothing within the

[1] *See e.g.*, P.L. 115-271, § 3292(a), adding new 21 U.S.C. § 802(57) ("The term 'suspicious order' may include, but is not limited to— (A)an order of a controlled substance of unusual size; (B)an order of a controlled substance deviating substantially from a normal pattern; and (C)orders of controlled substances of unusual frequency.")
[2] 21 C.F.R. §1301.74(b).
[3] P.L. 115-271, § 3292(b), adding new 21 U.S.C. § 832. However, there are a few differences between the statutory requirements concerning suspicious orders under the new CSA suspicious orders section and the regulatory requirements under 21 C.F.R. §1301.74(b). For example, the new statutory provision directs the registrant to notify the DEA Administrator in addition to the DEA Field Division Office about suspicious orders (the regulations specify only the latter as the point of contact) and requires the registrant to ensure that the system used to identify suspicious orders complies with federal and state privacy laws (the applicable regulations do not reference privacy laws). Compare P.L. 115-271, § 3292 (adding 21 U.S.C. § 832) with 21 C.F.R. § 1301.74(b).

new requirements for wholesalers and their employees relate to criminal liability under §841, and the reason is clear.

Employees of wholesalers, and, for that matter, wholesalers themselves, are too far removed from the ultimate end user and are not involved in the prescription process, which is the orientation of 21 U.S.C. §841. Mr. Doud is a former chief executive officer of a DEA registered wholesale distributor. He possessed no medical knowledge, interacted with no patients, and was never involved with the issuance of or the filling of a prescription. Nevertheless, the Government, without any statutory basis or legal precedent, charged Mr. Doud under §841 and it did so knowingly: "This prosecution is the **first of its kind**: Executives of a pharmaceutical distributor and the distributor itself have been charged with drug trafficking…" Geoffrey S. Berman, the United States Attorney for the Southern District of New York, said at a news conference announcing the charges against Mr. Doud. (Emphasis added).[4]

Further, the Government's brazen attempt to expand the scope of § 841 is underscored when considering the existing alternative statutes to enforce and penalize registrant conduct pertaining to suspicious orders, which is the gravamen of the factual allegations in the Indictment. Specifically, 21 U.S.C. § 832 is the recent statute—passed in October 2018—that would apply to registrants (and employees) in relation to suspicious orders. The relevance of 21 U.S.C. § 832 is further emphasized by the Government's Deferred Prosecution Agreement with Rochester Drug Co-Operative Inc. ("RDC"), Mr. Doud's former employer, alleging that it knowingly failed to furnish suspicious order reports to the DEA in violation of 21 U.S.C. §§ 842(a)(5) and (c)(2)—the CSA penalty provisions specifically dealing with suspect order

[4] *See* United States Department of Justice Press Release, *Manhattan U.S. Attorney And DEA Announce Charges Against Rochester Drug Co-Operative And Two Executives For Unlawfully Distributing Controlled Substances: First Ever Felony Criminal Charges Against a Distributor and its Executives for Illegal Distribution of Controlled Substances*, United States Department of Justice (April 23, 2019), https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-and-dea-announce-charges-against-rochester-drug-co-operative-and

violations under 21 U.S.C. § 832. Mr. Doud, on the other hand, was not charged with § 832 in all likelihood because the Government could not wreak the level of punishment it wants in this case. This conduct is not permitted because the Government cannot charge Mr. Doud under a statute that Congress does not authorize.

Finally, Mr. Doud did not have **fair notice** that his alleged conduct—conspiring with others to intentionally disregard suspect orders—violated 21 U.S.C. §§ 841 and 846. As the Supreme Court has countless times explained, the Fifth Amendment requires that a "statute, either standing alone or as construed, made [must make] it reasonably clear at the relevant time that the defendant's conduct was criminal."[5]

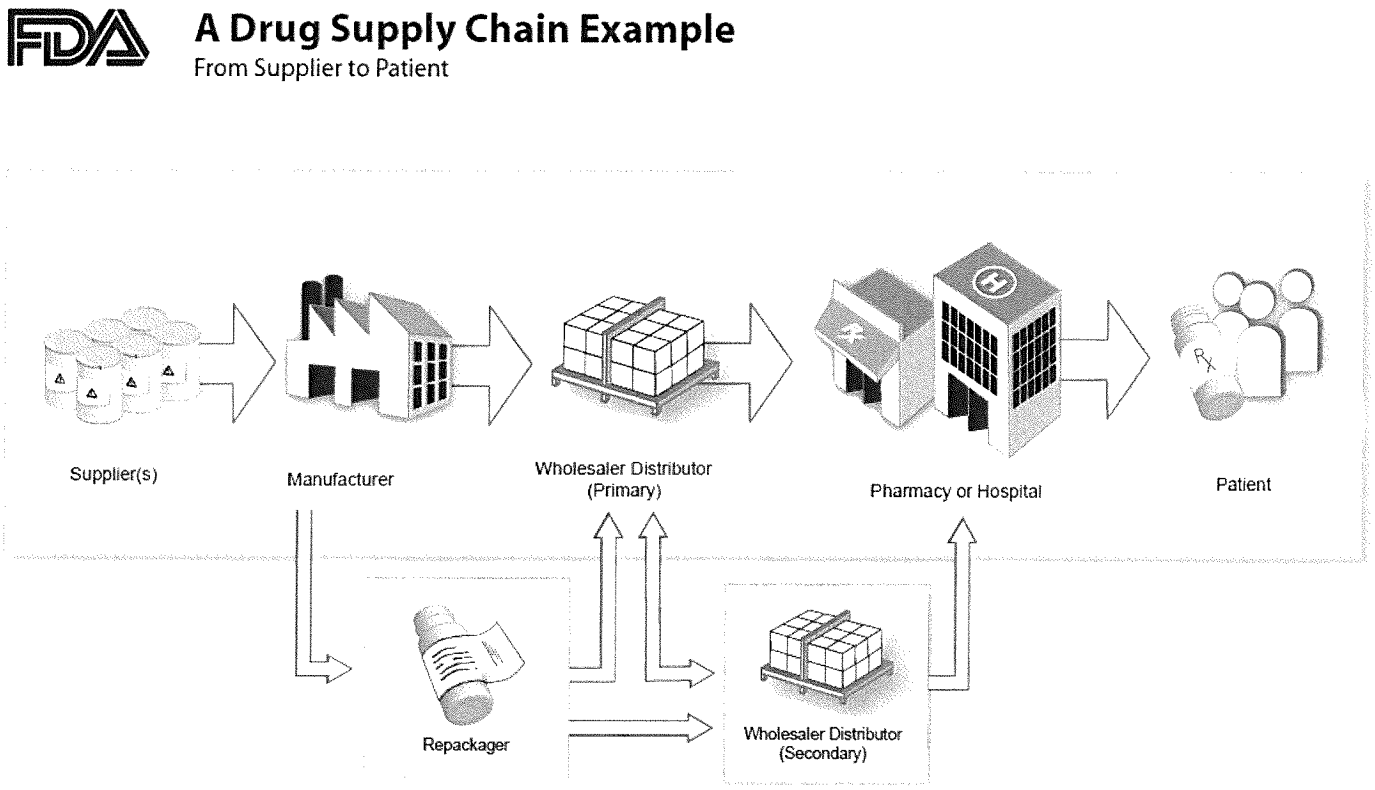
II. FACTUAL BACKGROUND

Laurence F. Doud's position in the pharmaceutical supply chain is critical to understanding why 21 U.S.C. § 841 does not apply to him. Mr. Doud is the former chief executive officer ("CEO") of RDC, a regional wholesale drug co-operative based in New York. The DEA has described the movement of a controlled substance from manufacture to the patient as follows:

> [A] controlled substance, after being manufactured by a DEA-registered manufacturer, may be transferred to a DEA-registered distributor for subsequent distribution to a DEA registered retail pharmacy. After a DEA-registered practitioner, such as a physician or a dentist, issues a prescription for a controlled substance to a patient (*i.e.*, the ultimate user), that patient can fill that prescription at a retail pharmacy to obtain that controlled substance. In this system, the manufacturer, the distributor, the practitioner, and the retail pharmacy are all required to be DEA registrants, or to be exempted from the requirement of registration, to participate in the process.[6]

[5] *See United States v. Lanier*, 520 U.S. 259, 267 (1997).
[6] DEA, *Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration*, 74 Fed. Reg. 3480, 3481 (January 21, 2009).

This is the pharmaceutical supply chain. RDC, like any other DEA registered wholesale distributor, provides controlled substances to pharmacies. These pharmacies then fill prescriptions written and provided to them by registered doctors and hospitals. As shown in the graphic on the following page,[7] as an employee of a wholesale distributor, Mr. Doud is entirely removed from the prescriptions process and the end user, the patient.



Actual prescriptions are issued and medications are dispensed to patients at the end of the supply chain. Despite *Mr. Doud's position in the pharmaceutical supply chain*—a primary wholesaler—he was arrested and indicted by a federal grand jury in the Southern District of New York on April 23, 2019, charging him with (1) conspiracy to distribute controlled substances, outside the scope of professional practice and not for a legitimate medical purpose, in violation

[7] Federal Drug Administration, *Graphic - A Drug Supply Chain Example*, www.fda.gov, https://www.fda.gov/drugs/drug-shortages/graphic-drug-supply-chain-example (last visited on September 28, 2019).

of 21 U.S.C. § 841 and 21 U.S.C § 846; and (2) conspiracy to defraud the United States in violation of 18 U.S.C. § 371.

A. Count One Of The Indictment

The Indictment against Mr. Doud alleges that he directed RDC to supply opioids to pharmacy customers despite the fact "that its own compliance personnel determined, and reported to Doud, [that the customers] were dispensing those drugs to individuals who had no legitimate medical need for them." Indictment at 2. The Indictment also alleges that "Doud and other members of RDC's senior management made the deliberate decision not to investigate, monitor, or report to the DEA pharmacy customers that they knew were diverting controlled substances for illegitimate use." *Id.* The Indictment goes on to allege that Mr. Doud directed RDC's compliance department not to report these issues to the DEA because it would likely result in the shutdown of the pharmacies in question. *Id.* at 3. Further, the Indictment alleges that Mr. Doud directed RDC's compliance department to report "red flags" with customers directly to him and "dismissed the concerns and rarely authorized the termination of business with the customers." *Id.* at 8.

Based on the aforementioned allegations, Count One charges Mr. Doud with the following:

Statutory Allegation

> 20. From at least in or about January 2012, up to and including in or about March 2017, in the Southern District of New York and elsewhere, LAURENCE F. DOUD III, the defendant, and others known and unknown, intentionally and knowingly did combine, conspire, confederate, and agree together and with each other to violate the narcotics laws of the United States.
>
> 21. It was a part and an object of the conspiracy that LAURENCE F. DOUD III, the defendant, and others known and unknown, would and did distribute and possess with intent to distribute

> controlled substances, outside the scope of professional practice and not for a legitimate medical purpose, in violation of 21 U.S.C. § 841 (a) (1).
>
> 22. The controlled substances that LAURENCE F. DOUD III, the defendant, and others known and unknown, conspired to distribute and possess with intent to distribute were (i) a quantity of mixtures and substances containing a detectable amount of oxycodone, in violation of 21 U.S.C. § 841(b) (1) (C), and (ii) 400 grams and more of mixtures and substances containing a detectable amount of fentanyl, in violation of 21 U.S.C. § 841(b) (1) (A).

Id. at 12-13.

III. ARGUMENT

Count One of the Indictment, which charges Mr. Doud with conspiracy to violate 21 U.S.C. §§ 841 and 846, is defective and must be dismissed, pursuant to Rule 12 of the Federal Rules of Criminal Procedure. Specifically, assuming the allegations in Count One as true, 21 U.S.C. § 841 does not apply to Mr. Doud because the alleged factual conduct is not and has never been charged under this statute. Outside of the "so-called street level" drug dealer, 21 U.S.C. § 841 is only applicable to doctors, pharmacists and their associates directly involved in the prescription process. Additionally, in the alternative, Count One must be dismissed as Mr. Doud did not have fair notice that his alleged conduct was prohibited by 21 U.S.C. § 841, in violation of his Fifth Amendment rights.

A. Count One Must Be Dismissed Under Federal Rule Of Criminal Procedure Rule 12(b)(3)(B) As It Alleges Conduct By Mr. Doud That Is Not Encompassed By 21 U.S.C. § 841

Count One must be dismissed under Federal Rule of Criminal Procedure Rule 12(b)(3)(B) as it fails to allege conduct by Mr. Doud encompassed within 21 U.S.C. § 841 and thus does not apply to him. Federal Rule of Criminal Procedure 12(b) states that at any time a case is pending, the defendant may move to dismiss an indictment on the grounds that it

possesses a defect. Fed. R. Crim. P. 12(b)(1) and (b)(3)(B). While Rule 12(b)(3)(B) delineates a few specific grounds for a finding a defect, it does not explicitly limit a dismissal of a defective indictment to only those bases.[8] *Id.*

A trial court must accept an indictment's factual allegations as true when considering a defendant's challenge. *United States v. Gotti*, 457 F. Supp.2d 411, 421 (S.D.N.Y. 2006). "[A] charge in an indictment is insufficient and must be dismissed when it does not describe conduct that is a violation of the criminal statute charged." *United States v. Smith*, 985 F. Supp. 2d 547, 561 (S.D.N.Y. 2014), *aff'd sub nom. United States v. Halloran*, 664 Fed. Appx. 23 (2d Cir. 2016); *see also United States v. Aleynikov*, 676 F.3d 71, 75–76 (2d Cir. 2012) (because "federal crimes are solely creatures of statute, a federal indictment can be challenged on the ground that it fails to allege a crime within the terms of the applicable statute").

Assuming the allegations in the Indictment as true, 21 U.S.C. § 841 does not apply to Mr. Doud because his conduct is not prohibited by the statute. Specifically, Mr. Doud's alleged conduct—an employee of a DEA registered wholesale distributor who, with other employees of the company, deliberately decided not to investigate, monitor, or report to the DEA, pharmacy customers that he knew were diverting controlled substances for illegitimate use—does not qualify him as an individual liable under 21 U.S.C. § 841. A review of the statute itself, the CSA, the corresponding federal regulations, and the applicable case law reveal that Mr. Doud's alleged conduct stated in Count One does not fall under the parameters of the statute.

[8] Fed. R. Crim. P. 12 (b)(3)(B) states, "[t]he following defenses, objections. and requests must be raised by pretrial motion…a defect in the indictment or information, **including**…." (Emphasis added).

1. Count One Is Defective As It Inappropriately Relies On DEA Regulations Explicitly And Specifically Applicable To Physicians And Pharmacists

As an initial matter, Count One is defective as it attempts to impose on Mr. Doud medical responsibilities by relying on language from Federal Regulations overtly directed to prescribers and pharmacists—"the defendant, and others known and unknown, would and did distribute and possess with intent to distribute controlled substances, **outside the scope of professional practice and not for a legitimate medical purpose**…" Indictment at 13. (Emphasis added). 21 C.F.R. § 1306.04 states that "[a] prescription for a controlled substance to be effective must be issued **for a legitimate medical purpose** by an individual practitioner acting in the **usual course of his professional practice**." 21 C.F.R. § 1306.04. (Emphasis added). Notably, this very language has been relied upon by the courts to expand 21 U.S.C. § 841 outside of the "so-called street level" drug dealer to specifically prosecute medical professionals. *See U.S. v Moore*, 423 U.S. 122, 136 (1975). While wholesale distributors are required to uphold various responsibilities,[9] the Federal Regulations spell out that the primary onus of monitoring and filling prescriptions rests directly with the pharmacies and practitioners, not with employees of wholesale distributors. *See* 21 C.F.R. § 1306.04.[10]

The CSA provides specific requirements that practitioners and pharmacists must observe when prescribing and dispensing controlled substances to patients for legitimate medical purposes. *See* 21 U.S.C. § 829. Federal Regulations hold both the prescribing practitioner and the pharmacist who fills the prescription responsible for ensuring that the controlled substance is

[9] *See e.g.,* 21 U.S.C. § 832 ("Each registrant shall—design and operate a system to identify suspicious orders for the registrant … and upon discovering a suspicious order or series of orders, notify the Administrator of the Drug Enforcement Administration….").

[10] "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner…[and] a corresponding responsibility rests with the pharmacist who fills the prescription." 21 C.F.R. § 1306.04.

properly prescribed and dispensed. In particular, 21 C.F.R. § 1306.04 provides that in order for a prescription for a controlled substance to be effective it "...must be issued **for a legitimate medical purpose** by an individual practitioner acting in the **usual course of his professional practice.**" 21 C.F.R. § 1306.04. (Emphasis added). The regulation also provides that, while "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner...a corresponding responsibility rests with the pharmacist who fills the prescription." *Id.*; *see also* 21 C.F.R. § 1306.06 ("a prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice"). Further, pursuant to the DEA's "Pharmacist's Manual" outlining the CSA, a pharmacist has certain duties:

> A pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription. Such a determination is made before the prescription is dispensed. The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances.

Drug Enforcement Administration, Pharmacists Manual: An Informational Outline of the Controlled Substances Act, 2010 Ed., at p. 30.[11]

Clearly, the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner and the pharmacist who fills the prescription. However, such responsibilities are **not** included in the narcotics distribution statute that Mr.

[11] *See also* Drug Enf't Admin., A Pharmacist's Guide to Prescription Fraud, https://www.deadiversion.usdoj.gov/pubs/brochures/pharmguide.htm (last visited Sept. 16, 2019) ("The law holds the pharmacist responsible for knowingly dispensing a prescription that was not issued in the usual course of professional treatment.").

Doud is charged with and do **not** apply to employees of DEA registered wholesale distributors. Regardless, the Government attempts, without any legal basis, to fuse responsibilities explicitly and specifically mandated to pharmacists and practitioners with the narcotics distribution statute charged, 21 U.S.C. § 841. To iterate, outside of the "so-called street level" drug dealer, 21 U.S.C. § 841 is only applicable to doctors and pharmacists and their associates directly involved in the prescription process. Not only is the Government attempting to meld exclusive statutes and regulations as it sees fit, but it is also imposing on employees of wholesale distributors the duty to detect and prevent violations of the CSA by licensed medical professionals, and to assess a legitimate medical purpose and scope of professional practice without any firsthand knowledge or medical training. This attempted distortion of the law by the Government is not only improper but also unfairly places employees of wholesale distributors in a tenuous position and must not be permitted. Such employees, like Mr. Doud, are not trained for this responsibility.

2. Mr. Doud's Alleged Conduct Does Not Fall Under 21 U.S.C. § 841 As The Government Disregards Relevant CSA And Regulatory Obligations Specifically Enacted To Police Mr. Doud's And RDC's Alleged Conduct

Conveniently, the Government has disregarded relevant obligations that the CSA and the Federal Regulations enforce specifically on registrants, including RDC, to reduce the potential diversion of controlled substances out of legitimate distribution channels.

The CSA regulates the manufacturing, distribution, and use of substances that have a detrimental effect on public health and welfare. *See* 21 U.S.C. § 801, *et seq*. Under 21 U.S.C. § 841(a)(1) of the CSA, it is unlawful "[e]xcept as authorized by the subchapter…for any person knowingly or intentionally…to…distribute…or possess with intent to distribute…a controlled

substance."[12] Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance must register with the DEA, unless they are exempt. *See* U.S.C. § 822. The CSA specifically permits an agent or employee of any registered distributor to lawfully possess any controlled substance. *Id.*

The CSA requires entities engaged in the manufacture, distribution, or dispensation of controlled substances to obtain a registration (license) from the Attorney General,[13] and establishes applicable registration requirements.[14] In essence, the CSA creates a "closed system" of distribution[15] in which distribution may lawfully occur among registered handlers of controlled substances, referred to as "registrants."[16] The Attorney General has the authority to deny, revoke, or suspend a registration under the CSA if he or she determines that the registrant is out of compliance with the mandates of the CSA, or that maintaining a registration would be inconsistent with the public interest. *See* 21 U.S.C. § 824. During Mr. Doud's employment at RDC, RDC effectively maintained its status as a registrant with the DEA, in accordance with 21 U.S.C. §§ 822-823, permitting its legal distribution of controlled substances. *See* **Exhibits B & C**.

Additionally, the CSA specifically requires distributors to maintain effective controls against diversion,[17] to prevent controlled substances from being directed to illegitimate

[12] The CSA defines "distribute" as "to deliver (other than by administering or dispensing) a controlled substance or listed chemical[,]" and defines "distributor" as "a person who so delivers a controlled substance or a listed chemical." 21 U.S.C. § 802(11).
[13] *See* 21 U.S.C. §§ 822 and 823; pursuant to 21 U.S.C. § 871(a), the Attorney General has delegated administration and enforcement of the CSA to the Administrator of the Drug Enforcement Administration. *See* 28 C.F.R. § 0.100.
[14] *Id.*
[15] Drug Enforcement Administration, *Electronic Prescriptions for Controlled Substances,* 75 Fed. Reg. 16235, 16237 (Mar. 31, 2010); *Gonzales v. Raich*, 545 U.S. 1, 2 (2005).
[16] According to 21 C.F.R. § 1300.02(b)(24), the term "registrant" means "any person who is registered [with the DEA] pursuant to [21 U.S.C. §§ 823 or 957]."
[17] The DEA has explained that the term "diversion," used in the context of the CSA, refers to "the redirection of controlled substances which may have lawful uses into illicit channels." Drug Enf't Admin., *Controlled Substances Quotas*, 83 Fed. Reg. 32,784 (July 16, 2018).

channels.[18] The CSA and the relevant regulations subject registrants to strict requirements regarding recordkeeping[19], maintaining the security of their controlled substance inventories[20], and reporting certain information to the DEA—most notably, investigating, monitoring and reporting suspect orders.[21] Distributors of controlled substances must design and operate a system to disclose suspicious orders of controlled substances, and they must report any discovered suspicious orders to the DEA. *See* 21 U.S.C. § 832 and 21 C.F.R. § 1301.74(b). Suspicious orders include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[22]

The heart of Count One alleges that Mr. Doud purposefully overlooked the red flags and deliberately failed to report the suspect orders. Indictment at 9-10, 14. However, the Government conveniently ignores the fact that Mr. Doud's and RDC's alleged conduct does not violate 21 U.S.C. § 841, but rather it potentially violates 21 U.S.C. § 832 (and supporting Regulation 21 C.F.R. § 1301.74(b)), which has its own separate penalty structure under the CSA for suspect order violations.[23] Specifically, 21 U.S.C. § 842 prohibits violations of a registrant's requirements under 21 U.S.C. § 832 and details the respective penalty provisions in support of 21 U.S.C. § 832. More particularly, 21 U.S.C. § 842(a)(5) prohibits "any person…to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter I."

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[18] *See* 21 U.S.C. § 823(b)(1) (requiring a registered distributor to maintain "effective control[s] against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."

[19] *See, e.g.,* 21 C.F.R. § 1304.11(a) ("Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken.... "); 21 U.S.C. § 827(a).

[20] *Id.* § 1301.71(a) ("All applicants and registrants shall provide effective controls to guard against theft and diversion of controlled substances."); *see also* 21 U.S.C. § 823(e)(1) (requiring the DEA Administrator, when determining whether a registration is consistent with the public interest, to consider if the applicant or registrant has in place "effective controls against diversion.").

[21] *See* 21 C.F.R. § 1301.74(b); 21 U.S.C. § 832.

[22] *Id.*

[23] *Id.* § 842(c) (providing penalties for committing prohibited acts set forth in *id.* § 842(a)).

21 U.S.C. § 842 further provides that violations of its regulatory requirements generally do not constitute a crime and that "imposition of a civil penalty ... shall not give rise to any disability or legal disadvantage based on conviction for a criminal offense,"[24] **unless** the violation was committed knowingly, in which case the CSA authorizes imprisonment of up to one or two years.[25] (Emphasis added). Thus, it is apparent, based on the express statutory language, that the criminal penalty for suspect order violations of 21 U.S.C. § 832 is a term of imprisonment of not more than one or two years.

Here, the factual allegations in support of Count One implicate suspect order violations under 21 U.S.C. § 832 and the corresponding penalty structure under 21 U.S.C. § 842. This is clearly supported by the Stipulation and Order of Settlement and Dismissal (the "Settlement Agreement") between the Government and RDC, which contains almost identical factual allegations as those in Count One in Mr. Doud's Indictment.[26] The Settlement Agreement specifically states that RDC "entered into a Deferred Prosecution Agreement…in connection with a three-count Information charging RDC, with, among other things, knowingly failing to furnish suspicious order reports to the DEA **in violation of 21 U.S.C. §§ 842(a)(5) and (c)(2)**" (emphasis added)—the aforementioned CSA provisions detailing the criminal penalties for suspect order violations. Yet, incredibly, the Government has elected to not only overlook these statutes and regulations in Mr. Doud's case, but to contort the application of an entirely incongruous statute—21 U.S.C. § 841. Recent investigations and enforcement actions by the DEA and the Department of Justice (DOJ) further stress the impropriety of Count One's reliance on 21 U.S.C. § 841.

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[24] 21 U.S.C. § 842(c)(3); *see also* 21 U.S.C. § (c)(1)(B) authorizing the imposition of a civil penalty of up to $10,000 for each violation.
[25] *Id.* § 842(c)(2).
[26] *See* **Exhibit D** at 3.

Over the past few years, the DEA and DOJ have used these regulatory requirements to police wholesale distributors executing suspicious orders of prescription opioids and sought considerable civil penalty settlements. For example, in January 2017, one of the largest U.S. drug distributors, McKesson Corporation ("McKesson"), agreed, *inter alia*, to pay a $150 million civil payment and suspend sales of controlled substances from distribution centers in Colorado, Ohio, Michigan and Florida for multiple years. This agreement was reached in order to resolve DEA allegations that McKesson had, in violation of CSA regulatory requirements and in the face of a 2008 settlement with the DOJ for similar issues, "failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances distributed to its independent and small chain pharmacy customers"—allegations closely analogous to Count One.[27] McKesson's 2017 Settlement Agreement and Release with the DOJ and DEA explicitly noted that McKesson accepted responsibility for violating 21 C.F.R. § 1301.74(b)[28] and 21 U.S.C. § 842(a)(5)[29].[30]

Another prominent pharmaceutical drug distributor, Cardinal Health, Inc. ("Cardinal Health"), agreed in December 2016 to pay $44 million to the federal government to settle allegations that it had failed to notify the DEA when it filled abnormally large and frequent orders for controlled substances requested by pharmacies located in Maryland, Florida, and New

[27] Press Release, U.S. Dep't of Just., Off. of Pub. Aff., McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs (Jan. 17, 2017), https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

[28] C.F.R. § 1301.74(b) requires distributors to design and operate a system to detect and report "suspicious orders" for controlled substances, as that term is defined in the regulation.

[29] Under 21 U.S.C. § 842(a)(5), it is unlawful for any person "to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter II."

[30] *See* United States Justice Department, Settlement Agreement and Release, www.justice.gov, https://www.justice.gov/opa/press-release/file/928471/download (last visited on September 28, 2019).

York, and that it had failed to maintain effective controls against diversion.[31] The settlement agreement between Cardinal Health and the federal government included an admission by the company that "from January 1, 2009 to May 14, 2012, it failed to report suspicious orders to the DEA as required by the CSA."[32]

Notably, in both of these enforcement actions, the DOJ and DEA applied the appropriate regulatory scheme and penalties related to suspect orders.[33] Further, they neither required admission of violations of 21 U.S.C. § 841 nor criminally prosecuted any individuals at McKesson or Cardinal Health. This is because it is well established that the scope of prosecutions under 21 U.S.C. § 841 only reaches doctors, pharmacists and their associates directly involved in the prescription process. Employees of wholesale distributors, such as McKesson and Cardinal Health, have not been prosecuted under the statute as they sit in a different position in the pharmaceutical supply chain than medical professionals and are not directly exposed to the end user. Despite definitive and recent precedent by the DOJ and DEA on substantially equivalent matters, the Government here has inexplicably elected to turn a blind eye to the suitable statutes and regulations concerning Mr. Doud's and RDC's alleged conduct, and has instead pursued a baseless prosecution.

3. The Government Is Attempting To Improperly Expand Liability Under 21 U.S.C. § 841 To Mr. Doud, Despite Courts' Holdings To The Contrary

Historically, 21 U.S.C. § 841 was used to prosecute "so-called street level" drug dealers, as it was "reserved for prosecution of those outside the legitimate distribution chain." *United States v. Moore*, 423 U.S. 122, 130 (1975). Accordingly, the vast majority of cases brought

[31] Press Release, U.S. Dep't of Just., U.S. Att'y Off., Dist. of Md., Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act (Dec. 23, 2016), https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act.
[32] *Id.*
[33] *See* 21 C.F.R. § 1301.74(b); 21 U.S.C. §§ 842(a)(5) and (c)(1)(B).

pursuant to § 841 dealt exclusively with these "so-called street level" drug dealers. *See United States v. Eldridge*, 528 Fed. Appx. 17 (2d Cir. 2013) (affirming conviction for possession of "crack cocaine with intent to distribute, *see* 21 U.S.C. § 841(a)(1)"); *United States v. Morris*, 509 Fed. Appx. 58, 62 (2d Cir. 2013) (upholding the district court's judgment of conviction for intent to distribute cocaine, pursuant to 21 U.S.C. § 841); *United States v. Hemmings*, 482 Fed, Appx. 640, 642 (2d Cir. 2012) (finding that the convictions for "distributing and possessing with intent to distribute…crack cocaine in violation of 21 U.S.C. § 841(a)(1)" was proper); *United States v. Brown*, 346 F Supp. 2d 522, 523 (S.D.N.Y. 2004) (noting that possessing marijuana with the intent to distribute is a "drug trafficking crime"). Clearly, this application of 21 U.S.C. § 841 does not pertain to Mr. Doud, as he is not, in any sense of the term, a "street level" drug dealer.

Besides "so-called street level" drug dealers, the only other persons who would have access to controlled substances were those in the medical profession. *See Moore*, 423 U.S. at 135-36. However, because medical professionals were registered under the CSA, it was generally thought that they were exempt from prosecution. *Id.* at 131-32. In fact, Dr. Moore, in *United States v. Moore*, made that exact argument. *Id.* at 131.

Specifically, Dr. Moore, a registered physician, was charged with the "knowing and unlawful distribution and dispensation of methadone…in violation of 21 U.S.C. § 841(a)(1)." *Id.* at 124. The government established that "between September 1971 and mid-February 1972 three District of Columbia pharmacies filled 11,169 prescriptions written by Dr. Moore…[which] covered some 800,000 methadone tablets." *Id.* at 126. The government also introduced evidence showing that Dr. Moore performed "only the most perfunctory examinations[s]" of his patients, that instead of relying on his own expertise as a doctor, he wrote prescriptions for amounts "requested by the patient," and that "on return visits…no physical examination was

performed and the patient again received a prescription for whatever quantity he requested." *Id.* at 126-27. Yet, Dr. Moore argued that "he had devised a new method of detoxification," even though he conceded that "he did not observe generally accepted medical practices." *Id.* at 126. Dr. Moore also argued that because he was registered under the CSA, he was exempt from prosecution. *Id.* at 131.

Despite Dr. Moore's protestations, the Court found that his "conduct exceeded the bounds of 'professional practice,' and that he acted like a drug 'pusher,'" not a doctor. *Id.* at 142. *See also Gonzales v. Oregon*, 546 U.S. 243, 269-70 (2006) (noting that the CSA "prohibit[s] a doctor from acting as a drug 'pusher' instead of a physician.").

In determining whether Dr. Moore was exempt from prosecution under 21 U.S.C. § 841, the Court looked to the legislative history of the CSA and noted that Congress enacted the CSA because it recognized that registrants had the "greatest opportunity" to divert "drugs from legitimate channels to illegitimate channels," and that these registrants "were responsible for a large part of the illegal drug traffic." *Moore*, 423 U.S. at 135. According to the Supreme Court, the CSA was intended "to limit a registered physician's dispensing authority to the course of his 'professional practice.'" *Id.* at 122. *See also Gonzales,* 546 U.S. at 269-70. (holding that "[t]he statute and our case law amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood.").

Upon finding that Moore's conduct was not within his professional practice, the Supreme Court held that "only the lawful acts of registrants are exempted." *Moore*, 423 U.S. at 131. The holding in *Moore* opened the door to the prosecution of physicians for the illegal distribution of

controlled substances under section 841, where there was sufficient proof of criminal intent. As the Court in *United States v. Vamos*, 797 F.2d 1146 (2d Cir. 1986) explained:

> Because they have been licensed as practitioners and registered under the CSA, they enjoy a privilege not extended to the layman. That privilege, based on the assumption that practitioners, by reason of their expertise and training, will be guided by generally accepted professional practice, carries with it greater responsibilities than those chargeable to the unlicensed person. These added responsibilities are essential to protect the public against abuse by "**registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion**."

United States v. Vamos, 797 F.2d 1146, 1153 (2d Cir. 1986) (citing *Moore*, 423 U.S. at 135) (emphasis added). Again, the court explicitly pointed out that the reason, in part, section 841 extended to Dr. Moore is precisely because registrant physicians like Dr. Moore have the great access to controlled substances and the greatest access to diversion by providing them directly to patients in scenarios where no legitimate medical purpose exists. *See also, United States v. Nelson*, 383 F. 3d 1227 (10th Cir. 2004) (prosecuting physician who signed "thousands" of hydrocodone prescriptions for an internet pharmacy without examining patients, and who had the proceeds from those sales wired to an offshore account); *United States v. Johnson*, 831 F.2d 124, 126-27 (6th Cir. 1987) (upholding the conviction of Dr. Johnson, who, after performing superficial exams, wrote prescriptions for drugs suggested by the patient, and who later wrote prescriptions for patients without ever performing examinations); *United States v. Green*, 511 F.2d 1062, 1067 (7th Cir. 1975) (finding that when "a physician acts without any legitimate medical purpose and beyond the course of professional practice by selling prescriptions that allow the bearer to obtain controlled substances, his conduct should be treated like that of any street-corner pill-pusher.").

While *Moore* and its progeny expanded the liability scheme under § 841, none of the cases extended liability to employees of wholesale distributors. Additionally, as discussed in detail below, these cases are all clearly distinguishable from the case at bar.

Pharmacists and pharmacy owners is another group of medical professionals to whom *Moore* has been applied. *See e.g., United States v. Steele*, 147 F.3d 1316 (11th Cir. 1998) (prosecuting a pharmacist for drug trafficking based on theory that he knowingly dispensed controlled substances based on forged prescriptions); *United States v. Hayes*, 595 F. 2d 258, 261 (5th Cir. 1979) (stating that the Court "did not think that Congress intended to allow pharmacists to aid doctors in becoming pushers. When a pharmacist fills a prescription that he knows is not a prescription within the meaning of the regulations he is subject to the penalties of § 841."); *Green*, 511 F.2d at 1064 (charging Green, the pharmacist and part-owner of the pharmacy, with knowingly and intentionally distributing…controlled substances pursuant to prescriptions which he knew were issued neither in the usual course of professional treatment nor for a legitimate medical purpose."). The courts extended liability to pharmacists because of the unique relationship that exists between a pharmacist and his or her patient. As noted in *United States v. DeBoer*, 966 F.2d 1066, 1069 (6th Cir. 1992), "a pharmacist had a responsibility not only to receive a prescription but to evaluate its propriety for the patient." No such relationship exists between a wholesale distributor and a patient.

Similarly, since *Moore*, individuals who have conspired with, or who aided and abetted a registrant to distribute controlled substances may be prosecuted under § 841. Unless an individual who assisted a medical professional distribute controlled substances "*reasonably* relied on the doctor's good faith in dispensing the controlled substance" he or she is a co-conspirator and is liable under § 841. *Vamos*, 797 F.2d at 1152. "Good faith in this context

means good intentions and the honest exercise of best professional judgment as to a patient's needs. It means that the doctor acted in accord with what he reasonably believed to be proper medical practice." *Id.* Notably, in *Vamos*, the nurse/office manager whose conviction was upheld on the grounds of aiding and abetting, had, among other things, "directed the staff to create false records for the drugs distributed…" *Id.* There is no question that she was not acting in good faith. *See also Johnson*, 831 F.2d at 129 (upholding conviction of non-physician clinic operator upon finding that his "close supervision of the clinic [was] sufficient to support the conclusion that he aided and abetted Dr. Johnson in the issuance of illegal prescriptions."); *United States v. Quinones*, 536 F. Supp.2d 267, 273 (E.D.N.Y. Feb. 19, 2008) (finding that the defendants, who operated websites, were being "prosecuted for conspiring with, and aiding and abetting, medical professionals…to distribute controlled substances outside the usual course of professional practice."); *United States v. Albert*, 675 F.2d 712, 714-15 (5th Cir. 1982) (noting that the doctor and his co-conspirators "discussed the possibility of trading merchandise for the drugs…[and that] [S]hortly thereafter, [his patients] brought a television set to Albert's office, in return for sixty Preludin pills and forty-eight Tuinal capsules.").

All of these cases are easily distinguishable from the instant case. First, unlike Mr. Doud, the individuals who were prosecuted were affirmatively and directly participated in the prescription process. Specifically, these individuals were either writing the prescriptions, filling the prescriptions, or were conspiring with or directly aiding and abetting the medical professionals in so doing.

Second, all of the individuals prosecuted in the above-mentioned cases were not passive participants, but rather, they were knowingly and intentionally assisting in diverting controlled substances for illegitimate use. In fact, these cases turned on the defendants' knowledge. *See*

United States v. Wiseberg, 727 Fed. Appx. 1, 5 (2d Cir. 2018) ("the evidence shows that [the defendant] knew that [the pharmacy's] business model was predicated on filling mail-order prescriptions for 'pill mills,' filled prescriptions against the objections of a licensed pharmacist, and did so in the face of ample indicia that customers lacked legitimate medical need."); *Vamos*, 797 F.2d at 1153-54 ("there was ample evidence from which the jury could infer beyond a reasonable doubt that the defendant nurse could not reasonably fail to know that Dr. Sugar was engaged in unlawful activity and that she intended to help him to so, which is the test."); *United States v. Limberopoulos*, 26 F.3d 245, 250-51 (1st Cir. 1994) (upholding jury's conviction of pharmacists who "knowingly sold narcotic drugs, without proper prescriptions, to drug addicts and drug dealers whom they knew had no legitimate medical need for the drugs.").

While this reasoning applies to the doctors who wrote the prescriptions and to the pharmacists who filled them, it applies equally to individuals who conspired with these medical professionals. *See Vamos*, 797 F.2d at 1153-54; *Johnson*, 831 F.2d at 129.

Here, given Mr. Doud's role as an employee of a DEA registered wholesale distributor, he could not have known, at the time the prescriptions were written, how or why they were written. Given Mr. Doud's position in the supply chain, he was simply too far removed from the prescription process. "A conviction under § 841(a)(1) requires the government to prove beyond a reasonable doubt that the drugs were distributed outside the usual course of professional practice." *See United States v. Seelig*, 622 F.2d 207, 213 (6th Cir. 1980). Here, the link is too tenuous, and the Government's prosecution of Mr. Doud must fail.

Third, in the cases in which defendants were convicted under 21 U.S.C. § 841, the defendants' behavior were undeniably outside the scope of their professional medical practices. *See Vamos*, 787 F.2d at 1151 ("The term 'professional practice' refers to generally accepted

medical practice.'"); *see also Hayes*, 595 F.2d at 261 ("Hayes possessed a supply of the doctor's prescription forms which he gave to customers to have filled out and signed by the doctor…[who] testified that…any prescriptions written by him were not written in the usual course of medical practice or for a legitimate medical purpose."); *Green*, 511 F.2d at 1067 (finding that selling a prescription constitutes acting "without any legitimate medical purpose and beyond the course of professional practice…"). Mr. Doud is not a medical professional; he is neither a physician, nor a nurse, nor a pharmacist, nor was he directly conspiring with any of these aforementioned medical professionals. Rather, Mr. Doud was an employee of a DEA registered wholesale distributor, and as discussed above, Mr. Doud was not involved in the dispensing or filling of prescriptions.

4. Recent Amendments To The CSA Further Corroborate That 21 U.S.C. § 841 Does Not Include Employees Of DEA Registered Wholesale Distributors

Due to the growing rise in drug overdose deaths involving opioids over the past two decades,[34] the federal government has been increasingly focused on addressing this public health crisis.[35] This resulted in the most comprehensive legislative response to the overprescribing and abuse of opioids and was signed into law by President Trump on October 24, 2018 in the form of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (P.L. 115-271) (the SUPPORT for Patients and Communities Act,

[34] *See* Centers for Disease Control and Prevention, Overdose Deaths Involving Opioids, Cocaine, and Psychostimulants—United States, 2015–2016, 67 MORBIDITY AND MORTALITY WEEKLY REPORT No. 12 (Mar. 30, 2018), https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6712-H.pdf.

[35] *See, e.g.,* THE PRESIDENT'S COMMISSION ON COMBATING DRUG ADDICTION AND THE OPIOID CRISIS: FINAL REPORT (2017); *see also The Drug Enforcement Administration's Role in Combating the Opioid Epidemic: Hearing Before the H. Comm. on Energy & Commerce, Subcomm. on Oversight and Investigations,* 115th Cong. (2018); *Combating the Opioid Crisis: Prevention and Public Health Solutions: Hearing Before the H. Comm. on Energy & Commerce, Subcomm. on Health,* 115th Cong. (2018).

or the SUPPORT Act).[36] The White House described the SUPPORT Act as the "single largest legislative package addressing a single drug crisis in history."[37] Specifically, Title III, subtitle B of the SUPPORT Act contains provisions that amend the CSA in various ways to address the opioid epidemic including safer disposing of unused medications,[38] increasing flexibility in providing medication-assisted treatment for opioid addiction,[39] providing drug manufacturers and distributors with certain Automated Reports and Consolidated Orders System data[40] and establishing annual production quotas for schedule I and II controlled substances.[41]

Most significantly, the SUPPORT Act also took specific and substantial steps to strengthen the requirements to detect and report suspicious orders. Prior to being amended by the SUPPORT Act, the statutory text of the CSA neither required registrants to design and manage a system to report to the DEA any suspicious orders of controlled substances[42] nor defined the term "suspicious orders." Chapter 9 of subtitle B, title III of the SUPPORT Act,[43] referred to as the "Preventing Drug Diversion Act of 2018," added a statutory definition of "suspicious order" to the CSA that in effect adopts the language of the existing regulatory definition.[44] These provisions also added a new section to the CSA entitled "Suspicious Orders," which requires a DEA registrant to take essentially the same actions as those required under the DEA regulation: (1) to devise and manage a system (conforming with applicable federal and state privacy laws) that will warn the registrant of suspicious orders of controlled substances, and (2) upon discerning a suspicious order or orders, to report to the DEA Administrator and the

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[36] Cong. Research Serv., R45164, *Legal Authorities Under the Controlled Substances Act to Combat the Opioid Crisis* (2018).
[37] White House, Ending America's Opioid Crisis, https://www.whitehouse.gov/opioids/ (last visited Sept. 10, 2019).
[38] *See, e.g.,* U.S.C. § 822(g)(5)(B)(iii), as added by P.L. 115-271, § 3222(a).
[39] *See, e.g.,* P.L. 115-271, §§ 3201-3204.
[40] *See, e.g.,* P.L. 115-271 § 3273(a)(2), adding new 21 U.S.C. § 827(f)(1).
[41] *See* P.L. 115-271, § 3282(a), adding new 21 U.S.C. § 826(a)(2).
[42] Such requirements appeared in DEA regulation 21 C.F.R. §1301.74(b).
[43] P.L. 115-271, §§ 3291-3292.
[44] P.L. 115-271, § 3292(a), adding new 21 U.S.C. § 802(57).

Special Agent in Charge of the DEA Field Division Office.[45] The SUPPORT Act also established a maximum criminal fine of $500,000 for registered manufacturers or distributors of opioids who intentionally fail to report suspicious orders for opioids.[46]

While the SUPPORT ACT was drafted and passed with the primary purpose of combating the opioid crisis, Congress spurned an apparent opportunity to amend the CSA to include Mr. Doud's alleged conduct—an employee of a wholesale distributor who, with other employees at the company, intentionally decided not to investigate, monitor, or report suspicious orders to the DEA that he knew were diverting controlled substances for illegitimate use—as part of the definition of illicit distribution under 21 U.S.C. § 841. Rather than alter the definition to accommodate such conduct, Congress instead supplemented other specific aspects of the CSA to combat opioid abuse. In amending the CSA to include provisions expressly concerning suspect orders, Congress could have just as easily declared that the intentional circumvention of these provisions was an illegal statutory distribution under 21 U.S.C. § 841. Instead, Congress chose to leave the statutory definition of illicit distributions of controlled substances as is, rather than classify Mr. Doud's alleged conduct under 21 U.S.C. § 841. In fact, the SUPPORT ACT specifically recognized that the intentional failure to report suspicious orders of opioids by registered distributors was punishable with a maximum fine of $500,000.[47] Evidently, Congress did not believe that including the intentional disregard of suspicious orders by an employee of a wholesale distributor as illicit distribution under 21 U.S.C. § 841 was an effective or necessary mechanism in combatting our country's ongoing opioid epidemic and declined a clear opportunity to expand the statutory definition of illicit distribution under 21 U.S.C. § 841.

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[45] P.L. 115-271, § 3292(b), adding new 21 U.S.C. § 832.
[46] P.L. 115-271, § 3273(c)(2)(B)(ii), adding new 21 U.S.C. § 842(c)(2)(D).
[47] *Id.*

B. As Applied To Mr. Doud, Count One Should Be Dismissed As 21 U.S.C. § 841 Does Not Provide Fair Notice That The Intentional Disregard Of Suspect Orders By An Employee Of A DEA Registered Wholesale Distributors Is Penalized Under § 841

Alternatively, given the clear language of the statute, registrant's demarcated responsibilities, and the limited scope of the relevant case law, Mr. Doud did not have fair notice that his alleged conduct violated 21 U.S.C. §§ 841 and 846. Thus, Count One should be dismissed as 21 U.S.C. § 841 is unconstitutionally vague as applied to Mr. Doud. The void-for-vagueness doctrine derives from the constitutional guarantee of due process..." *Birgrx v. Phillips*, 619 F.3d 187, 197 (2d Cir. 2010). Due process requires that a criminal statute "give a person of ordinary intelligence fair notice that his contemplated conduct is forbidden by the statute." *Colautti v. Franklin*, 439 U.S. 379, 390 (1979). The Supreme Court has noted that "[t]he threshold question in any vagueness challenge is whether to scrutinize the statute for intolerable vagueness on its face or whether to do so only as the statute is applied in the particular case." *Schwartzmiller v. Gardner*, 752 F.2d 1341, 1346 (1984). "[T]he touchstone is whether the statute, either standing alone or as construed, made it reasonably clear at the relevant time that the defendant's conduct was criminal." *United States v. Lanier*, 520 U.S. 259, 267 (1997).

Here, 21 U.S.C. § 841 is constitutionally vague as applied to Mr. Doud because he did not have adequate notice, either through the language of the statute or through the case law applying the statute, that his alleged actions triggered a violation. As described above, neither the CSA nor the Federal Regulations provide sufficient notice that conduct surrounding the execution of suspect orders by an employee of a DEA registered wholesale distributor violates 21 U.S.C. § 841. In conjunction with 21 U.S.C. §§ 822-823, 21 U.S.C. § 841 explicitly permits distribution by registrants and their employees. Notably, the CSA separately addresses prohibitions and punishments concerning suspect orders. *See* 21 U.S.C. § 832 and 21 U.S.C. §

842(c)(2)(D). The Federal Regulations also specifically delegate the responsibility for the proper prescribing and dispensing of controlled substances to licensed professionals, that is, the prescribing physician and the pharmacist who fills the prescription. *See* 21 C.F.R. § 1306.04. Based on a plain review of the structure and language of the CSA and the corresponding Federal Regulations, an employee of a DEA registered wholesale distributor of drugs has no reasonable basis to think that he could be liable under 21 U.S.C. § 841 for conduct involving the investigation, monitoring or execution of suspect orders.

Further, no court has ever applied the narcotics statute of 21 U.S.C. § 841 to the conduct at issue here. To interpret 21 U.S.C. § 841 to prohibit Mr. Doud's alleged conduct raises serious constitutional issues. "[A] deprivation of the right of fair warning can result not only from vague statutory language but also from an unforeseeable and retroactive judicial expansion of narrow and precise statutory language." *Bouie v. City of Columbia*, 378 U.S. 347, 378 (1964). "[A]n unforeseeable judicial enlargement of a criminal statute, applied retroactively, operates precisely like an *ex post facto* law, such as Art. I, § 10, of the Constitution forbids." *Id.* at 352. As described above, 21 U.S.C. § 841 has been judicially expanded to only include doctors, pharmacists and others directly involved in a medical practice acting outside the usual course of professional practice. There has been no judicial interpretation in any federal court permitting the enforcement of 21 U.S.C. §§ 841 and 846 against employees of DEA registered distributors, even in the conspiracy context. While many courts have considered and declined to apply the vagueness doctrine in relation to 21 U.S.C. § 841,[48] these unsuccessful challenges have focused

[48] *See, e.g.*, *United States v. Rosenberg*, 515 F.2d 190, 197 (9th Cir.), *cert. denied*, 423 U.S. 1031(1975); *United States v. Collier*, 478 F.2d 268, 270 (5th Cir. 1973); *United States v. Darji*, 609 F. App'x 320, 334 (6th Cir. 2015); *United States v. Orta-Rosario*, 469 F. App'x 140, 143 (4th Cir.), *cert. denied*, 133 S. Ct. 311 (2012); *United States v. Brickhouse*, No. 3:14-CR-124, 2016 WL 2654359, at *4 (E.D. Tenn. Mar. 30, 2016); *Quinones*, 536 F. Supp. 2d at 274; *United States v. Birbragher*, 576 F. Supp. 2d 1000, 1013 (N.D. Iowa 2008), *aff'd,* 603 F.3d 478 (8th Cir. 2010); *United States v. Prejean*, 429 F. Supp. 2d 782, 805 (E.D. La. 2006).

on whether section 841 was vague as applied to health care professions. *See e.g., United States v. Jobe*, 487 F.2d 268, 269 (10th Cir. 1973) (the statute "is not a model of clarity," but it is clear and inescapable that when a medical practitioner issues a prescription not for a medical purpose and not in the usual course of his professional practice, he violates the statute). However, in this instance, Mr. Doud is clearly not directly involved in a medical practice and respectfully requests the Court to consider the impropriety of applying 21 U.S.C. § 841 to him.

If this Court were to apply a broader construction of the statute than that approved in *Moore* and its progeny (holding registered medical professionals and those that directly work with them subject to prosecution under 21 U.S.C. §§ 841(a)(1) when their activities fall outside the usual course of professional practice), it would be precisely the sort of "unforeseeable judicial enlargement of a criminal statute" that the Due Process Clause forbids, and it would raise severe questions about the validity of 21 U.S.C. § 841 as a whole owing to its failure to provide adequate notice of the conduct it forbids. Because of inherent ambiguity and potential for abuse in expanding 21 U.S.C. § 841 beyond medical professionals that act outside the usual court of professional practice, this Court should read the statute to avoid such constitutional difficulties and dismiss Count One for being void for vagueness as applied to Mr. Doud.

IV. CONCLUSION

For the reasons set forth herein, Mr. Doud respectfully requests that this Court, pursuant to Rule 12(b)(3)(B) of the Federal Rules of Criminal Procedure and the Fifth Amendment of the Constitution, dismiss Count One of the Indictment alleging narcotics conspiracy because it does not encompass Mr. Doud's alleged conduct under 21 U.S.C. § 841, and because it is unconstitutionally vague as applied to Mr. Doud.

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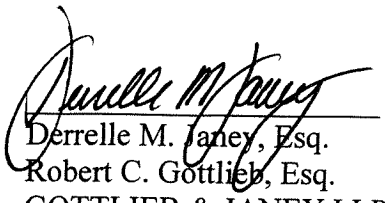
Dated: New York, NY
October 1, 2019

By: 

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